# DRAFT
# Potential Risks from Consuming Breast Milk

One of the remaining questions we have for the Portland Harbor human health risk assessment is whether to evaluate potential risks to infants from consuming chemicals in breast milk as a result of maternal exposure from eating contaminated fish. And if we do include this pathway, we need to agree on a risk assessment approach. To evaluate the feasibility of conducting a risk assessment based on exposure to breast milk, I followed the approaches presented in the documents provided by Dana. These include the Human Health Risk Assessment for the GE/Housatonic River Site, dated February 2005, the *Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities*, EPA530-R-05-006, dated September 2005, and the preliminary *Environmental Risk Assessment Work Plan for the Hanford Tank Waste Treatment and Immobilization Plant* (I'm not sure of the date). I limited my evaluation to total PCBs. However, the methodology is applicable to other chemicals, such as PCB congeners, chlorinated dibenzo-*p*-dioxins, and DDT.

My conclusion based on these preliminary calculations is that it is feasible to include exposure to breast milk in the Portland Harbor inwater risk assessment, and that this is an important exposure pathway.

**GE/Housatonic Report**

First, I have a few comments on the equations used in the GE/Housatonic report. In Equation 1 (page 10-16), the units provided do not match. If ADD is reported in mg/kg/day, then the conversion factor should be $10^6$ ng/mg, not $10^3$ ng/mg. However, I don't see a need for any conversion factor, because the tables report $C_{milk\text{-}fat}$ in units of mg/kg. The calculations are not three orders of magnitude off, so if a conversion was used, it appears to have been correct.

In Equation 2 (page 10-17), IR should be in units of g/day, not mg-tissue/day. Again, I think the calculations were performed correctly. I was able to duplicate the calculation of ADD shown in Table 10-16. Unfortunately, I was not able to duplicate the $C_{milk\text{-}fat}$ calculations (Predicted RME Milk Fat in Table 10-16, or CTE in Table 10-17). My calculations for $C_{milk\text{-}fat}$ are higher by a factor of 11. For instance, for RME total PCB, I get 52 mg/kg-lipid instead of 4.6 mg/kg-lipid. One possible source of error is the half life. I used the CTE value of 6 years, and assumed that this also applied to RME. I could not tell from the text (Section 10.3.1.2, page 10-22) if this is a correct assumption. It seems unlikely that a half life of 0.5 years would be used (necessary to get the values shown in Tables 10-16 and 10-17, if my calculations are correct). The other values in Equation 1 ($f_1 = 0.9$ and $f_2 = 0.3$) seem well defined, so I have not identified the problem. I would appreciate it if someone else would check the calculation of $C_{milk\text{-}fat}$ in the Housatonic report.

**Preliminary Application to Portland Harbor**

I mostly used the nomenclature presented in the EPA combustion risk assessment guidance document, modified to make the equations no longer specific to dioxins or the inhalation pathway, and instead make them appropriate to fish consumption. The key concept is that the concentration of a chemical in milk can be calculated from the long-term body burden in the mother. We start with the average daily intake of chemicals from fish consumption (modified from Table C-1-4):

$$ADD_{mother} = \frac{C_{fish} \times IR_{fish} \times CF \times F_{fish}}{BW}$$

Where:

| | | |
|---|---|---|
| $ADD_{mother}$ | = | Average daily dose to mother (mg/kg/day) |
| $C_{fish}$ | = | Chemical concentration in fish (assume 1 mg/kg) |
| $IR_{fish}$ | = | Ingestion rate of fish (142.4 g/day) |
| CF | = | Conversion factor (0.001 kg/g) |
| $F_{fish}$ | = | Fraction of fish contaminated (1) |
| BW | = | Body weight (66 kg) |

The ingestion rate is for fishers subsisting on resident fish. The fish consumption rate is an annualized rate (*i.e.*, it includes the assumption that fish are eaten throughout the year, so exposure frequency, exposure duration, and averaging time are not included in the equation). I did not include loss of PCBs during cooking (assumed to be 25 percent in the Housatonic study). For body weight, I did not see a good reason to use the guidance value of 70 kg (average adult weight), and instead used the average female weight of 66 kg.

For simplicity, I performed the calculations assuming a unit total PCB concentration of 1 mg/kg in fish tissue. This is actually close to the mean PCB concentration measured in Portland Harbor resident fish, but mostly this was done for convenience.

$$ADD_{mother} = 1 \text{ mg/kg} \times 142.4 \text{ g/day} \times 0.001 \text{ kg/g} \times 1 / 66 \text{ kg} = 0.0022 \text{ mg/kg/day}$$

EPA has found that dietary intake of PCBs during pregnancy and lactation is only weakly correlated with PCB concentrations in human milk. The more important determinant is long-term consumption. The following equation is used to calculate the PCB concentration in milk fat. This assumes that maternal long-term intake occurs over a period greater than the PCB half-life, and that PCB concentrations in breast milk reflect the maternal body burden.

$$C_{milkfat} = \frac{ADD_{mother} \times h \times f1}{\ln(2) \times f2}$$

Where:

| | | |
|---|---|---|
| $C_{milkfat}$ | = | PCB concentration in milkfat (mg/kg-lipid) |
| $ADD_{mother}$ | = | Average daily dose to mother (mg/kg/day) |
| h | = | Half-life of PCB (7 years = 2555 days) |
| f1 | = | Fraction of ingested PCB stored in fat (0.9) |
| f2 | = | Fraction of mother's weight that is fat (0.3 lipidBW/totalBW) |

$$C_{milkfat} = \frac{0.0022 \text{ mg/kg-totalBW/day} \times 2555 \text{ days} \times 0.9}{0.693 \times 0.3 \text{ (lipidBW/totalBW)}}$$

$$= 24 \text{ mg/kg-lipid}$$

Average daily doses to the infant are calculated separately for carcinogenic and noncarcinogenic effects.

For carcinogenic effects, the average daily dose is:

$$ADD_{child} = \frac{C_{milkfat} \times IR_{milk} \times f3 \times f4 \times EDc \times EFc}{ATc \times BWc}$$

Where:

| | | |
|---|---|---|
| $ADD_{child}$ | = | Average daily dose for breast-feeding child (mg/kg/day) |
| $C_{milkfat}$ | = | Concentration of chemical in milk fat (mg/kg-lipid) |
| $IR_{milk}$ | = | Ingestion rate of breast milk (0.69 kg/day) |
| f3 | = | Fraction of breast milk that is fat (0.04) |
| f4 | = | Fraction of ingested PCB that is absorbed (0.9) |
| EDc | = | Exposure duration of breast-feeding child (1 year) |
| EFc | = | Exposure frequency of breast-feeding child (365 days/year) |
| ATc | = | Averaging time – carcinogen (70 years x 365 days/year) |
| BWc | = | Body weight of breast-feeding child (9.4 kg) |

$$ADD_{child} = \frac{24 \text{ mg/kg-lipid} \times 0.69 \text{ kg/day} \times 0.04 \times 0.9 \times 1 \text{ yr} \times 365 \text{ day/yr}}{70 \text{ yr} \times 365 \text{ day/yr} \times 9.4 \text{ kg}}$$

$$= 0.00091 \text{ mg/kg/day}$$

The excess lifetime cancer risk is:

$$CR_{child} = ADD_{child} \times SFo$$

Where:

| | | |
|---|---|---|
| $CR_{child}$ | = | Excess lifetime cancer risk to child from breast feeding |
| SFo | = | Cancer slope factor – oral [2 $(mg/kg/day)^{-1}$ for total PCBs] |

$$CR_{child} = 0.00091 \text{ mg/kg/day} \times 2 \text{ (mg/kg/day)}^{-1} = 2 \times 10^{-3}$$

For non-cancer effects, the average daily dose is:

$$ADD_{child} = \frac{C_{milkfat} \times IR_{milk} \times f3 \times f4 \times EDc \times EFc}{ATc \times BWc}$$

Where:

| | | |
|---|---|---|
| $ADD_{child}$ | = | Average daily dose for breast-feeding child (mg/kg/day) |
| $C_{milkfat}$ | = | Concentration of chemical in milk fat (mg/kg-lipid) |
| $IR_{milk}$ | = | Ingestion rate of breast milk (0.69 kg/day) |
| f3 | = | Fraction of breast milk that is fat (0.04) |
| f4 | = | Fraction of ingested PCB that is absorbed (0.9) |
| EDc | = | Exposure duration of breast-feeding child (1 year) |
| EFc | = | Exposure frequency of breast-feeding child (365 days/year) |
| ATnc | = | Averaging time – non-carcinogen (= EDc x EFc) |
| BWc | = | Body weight of breast-feeding child (9.4 kg) |

$$ADD_{child} = \frac{24 \text{ mg/kg-lipid} \times 0.69 \text{ kg/day} \times 0.04 \times 0.9 \times 1 \text{ yr} \times 365 \text{ day/yr}}{1 \text{ yr} \times 365 \text{ day/yr} \times 9.4 \text{ kg}}$$

$$= 0.063 \text{ mg/kg/day}$$

The hazard quotient is:

$$HQ_{child} = \frac{ADD_{child}}{RfD}$$

Where:

$HQ_{child}$ = Hazard quotient for breast-feeding child

RfD = Non-cancer reference dose ($2 \times 10^{-5}$ mg/kg/day for total PCBs)

$$HQ_{child} = 0.063 \text{ mg/kg/day} / 2 \times 10^{-5} \text{ mg/kg/day} = 3{,}200$$

Except for the fish consumption rate, the above exposure factor values were taken from EPA's combustion risk assessment guidance. These values seem reasonable to me, after checking EPA's Exposure Factors Handbook (Chapter 14 for breast milk intake, and Chapter 7 for body weight).

Using this approach, the excess lifetime cancer risk for a child consuming total PCBs in breast milk for one year is approximately $2 \times 10^{-3}$. By coincidence, this is the same as the risk to the mother from long-term (30 years) fish consumption. Both risks are, of course, unacceptable compared with $1 \times 10^{-6}$. The calculated risks are based on a total PCB concentration in fish of 1 mg/kg. Because risks are directly proportional to concentration, potential risks from other fish concentrations can be easily calculated. From what I have seen, though, 1 mg/kg PCB in fish tissue is a good initial approximation of total PCB concentrations in fish tissue collected during Round 1. Arithmetic mean total PCB concentrations throughout the ISA are: smallmouth bass, 0.91 mg/kg; carp, 1.7 mg/kg; brown bullhead, 0.42 mg/kg; and black crappie, 0.13 mg/kg.

For non-cancer effects, the hazard quotient is 3,200 for a child consuming total PCBs in breast milk. This is a much higher HQ than I expected. The RfD is based on LOAELs developed from studies on monkeys. The health effects included inflammation of glands in the eye, distorted growth of finger and toe nails, and decreased antibody responses. The uncertainty factors used in the derivation of the human health RfD total 300 (I think this is rounded from 270), applied to an animal LOAEL of 0.005 mg/kg/day. The calculated HQ from consumption of breast milk is an order of magnitude greater than the uncertainty factor.

Another uncertainty is the application of the RfD to one year of exposure, rather than long-term (lifetime) exposure. I think it is appropriate to apply the RfD in this case, considering the potential sensitivity of infants to adverse health effects. I also looked at the reduction in body burden of PCB during a year of breast feeding to see if that could result in substantially reduced concentrations in breast milk. If the concentration in milk fat ($C_{milk}$ = 24 mg/kg-lipid) is equivalent to the concentration in other tissues ($C_{lipid}$), then the body burden in the mother is:

$C_{lipid}$ x $BW_{mother}$ x f2 =

24 mg/kg-lipid x 66 kg-BW x 0.3 kg-lipid/kg-BW = 480 mg PCB

The loss of mass during one year of breast feeding is:

$IR_{milk}$ x $C_{milkfat}$ x f3 x 365 days =

0.69 kg/day x 24 mg/kg-lipid x 0.04 kg-lipid/kg-milk x 365 days = 240 mg PCB

This implies that a mother will lose approximately half of her PCB body burden (240 mg / 480 mg) during a year of breast feeding, assuming that there is no additional consumption of contaminated fish during this period. This simplistic evaluation is consistent with EPA's determination (summarized in the Housatonic report) that there will be a 20 percent reduction of PCBs in the mother every three months. Over a year, this would correspond to a reduction of $1 - (0.8)^4 = 0.6$, or a 60 percent reduction in PCB mass after one year. The reduction in mass (and concentration) averaged over the course of the year would be about half of this value. I do not consider it appropriate at this time to refine the calculations to include reduction in mass by at most a factor of 2.

At sites such as the Housatonic, EPA presented the potential risks from breast milk consumption as a ratio to background risk rather than as an excess lifetime cancer risk or HQ. The background total PCB concentration that they use is 0.32 mg/kg-lipid in milk. (According to my calculations using the Housatonic data, they are 160 times the background value, not the 14.5 times reported). Using the assumed total PCB concentration of 1 mg/kg in fish tissue and the assumed subsistence fish consumption rate, the calculated total PCB concentration in breast milk of 24 mg/kg-lipid is 75 times background. This would correspond to an excess lifetime cancer risk 75 times the excess risk due to background PCB concentrations, and also a hazard quotient 75 times background.

I can understand the sensitivity about presenting potential risks that are uncertain, and that may discourage breast-feeding despite the known benefits. However, in general I'm inclined to calculate risk or HQ. I also think it may be mandated by Oregon rules. In the lower Willamette, consumption of resident fish by lactating mothers is already discouraged by the PCB fish advisory. The Oregon DHS advisory states that: "Women of childbearing age, particularly pregnant or breastfeeding women, children and people with weak immune systems, thyroid or liver problems, should avoid eating resident fish from Portland Harbor, especially carp, bass and catfish." The results presented here appear to quantitatively support the advisory.

- Mike Poulsen